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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William P. Christie
CHRISTIE PARKER & HALE LLP
Post Office Box 7068
Pasadena, CA 91109-7068

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,941	PHAN ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) *1-50,54-57,64 and 67-108* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *51-53,58-63,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on August 31, 2005 has been entered. The claims pending in this application are claims 1-115 wherein 1-50, 54-57, 64, and 67-115 have been withdrawn due to restriction requirement and species election (see applicant's remarks filed on December 13, 2004). Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of the response filed on August 31, 2005.

Election/Restrictions

2. This application contains claims 1-50 and 67-115 drawn to an invention nonelected without traverse filed on August 2, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. New Matter

Claims 51-53, 58-63, 65, and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "non-covalently bound capture agents are selectively removed" is added to the newly amended independent claim 51. Although the specification describes that heat treatment can be used to selectively remove non-covalently bound DNA probes from a solid phase (see page 56, second and third paragraph), the specification fails to define or provide any disclosure to support such claim limitation. Note bound capture agents recited in claim 51 is not only limited to non-covalently bound DNA probes. For example, see claims 54-57 of this instant application.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application."

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 51, 52, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen (US Patent No. 6,342,349 B1, filed on July 21, 1998).

The applied reference has a common inventor, Jorma Virtanen, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 51, Virtanen teaches that an optical bio-disc comprising a substrate having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc (see abstract, column 9, lines 51-54 and Figure 11B); a target zone associated with said substrate, said target zone disposed at a predetermined location relative to said substrate, a heated active layer associated with said target zone (see Figure 2C and column 16, second paragraph, an active layer treated by heat in order to cleave the spacer molecule in Figure 2B); and a plurality of capture agents attached to said active layer (ie., locations on the disc having multiple identical oligonucleotides, see Figure 2C) so that when said substrate is rotated, said capture agents remain attached to said active layer to thereby maintain a number of said capture agents within said target zone (see column 8, lines 20-26, columns 16, lines 51-67 and column 17, lines 1-32, and Figure 2B). Although Virtanen does not teach "non-covalently bound capture agents are selectively removed" as recited in claim 51, Virtanen teaches that oligonucleotides are covalently attached to the solid support substrate (see column 26, lines 44-58). Since "non-covalently bound capture agents are selectively removed" recited in

claim 51 is a method step, it is known that the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claim 51 does not require that a dual bead complex is on the optical bio-disc and the optical disc taught by Virtanen has an ability to bind to a dual bead complex when the dual bead complex including covalently bound probes is introduced into said target zone and said capture agent sequesters said dual bead complex, claim 51 is anticipated by Virtanen.

Regarding claim 52, since Virtanen teaches that the oligonucleotide side members are adapted to bind complementary single strands of nucleic acids that may be present in a test sample (see column 16, lines 51-67), Virtanen discloses that said capture agent is a single stranded oligonucleotide sequence.

Regarding claim 58, Virtanen teaches that said capture agent (ie., the oligonucleotide) contains an amino group (see column 26, lines 45-58).

Therefore, Virtanen teaches all limitations recited in claims 51, 52, and 58.

Response to Arguments

In page 21, fourth and fifth paragraphs of applicant's remarks, applicant argues that "[V]irtanen does not disclose a 'heat-treated active layer' and 'wherein non-covalently bound capture agents are selectively removed.' Thus, Applicants respectfully submit that Virtanen does not disclose all of the limitations of any of claims 51, 52, 58, and 61-66, as now amended".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because Virtanen does teach heat-treated active layer (see above rejection). Although Virtanen does not teach "non-covalently bound capture agents are

selectively removed" as recited in claim 51, Virtanen teaches that oligonucleotides are covalently attached to the solid support substrate (see page 60, first paragraph). Since "non-covalently bound capture agents are selectively removed" recited in claim 51 is a method step, it is known that the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

7. Claims 51, 52, and 58 are rejected under 35 U.S.C. 102(a) as being anticipated by Virtanen (WO 00/05582, published on February 3, 2000).

Regarding claim 51, Virtanen teaches that an optical bio-disc comprising a substrate having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc (see page 21, lines 10-13 and Figure 11B); a target zone associated with said substrate, said target zone disposed at a predetermined location relative to said substrate, a heated active layer associated with said target zone (see Figure 2C and page 36, second paragraph, an active layer treated by heat in order to cleave the spacer molecule in Figure 2B); and a plurality of capture agents attached to said active layer (ie., locations on the disc having multiple identical oligonucleotides) so that when said substrate is rotated, said capture agents remain attached to said active layer to thereby maintain a number of said capture agents within said target zone (see page 17, lines 14-20, pages 37-39, and Figure 2B). Although Virtanen does not teach "non-covalently bound capture agents are selectively removed" as recited in claim 51, Virtanen teaches that oligonucleotides are covalently attached to the solid support substrate (see page 60, first paragraph). Since "non-covalently bound capture

agents are selectively removed" recited in claim 51 is a method step, it is known that the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claim 51 does not require that a dual bead complex is on the optical bio-disc and the optical disc taught by Virtanen has an ability to bind to a dual bead complex when the dual bead complex including covalently bound probes is introduced into said target zone and said capture agent sequesters said dual bead complex, claim 51 is anticipated by Virtanen.

Regarding claim 52, since Virtanen teaches that the oligonucleotide side members are adapted to bind complementary single strands of nucleic acids that may be present in a test sample (see page 37, lines 19-25), Virtanen discloses that said capture agent is a single stranded oligonucleotide sequence.

Regarding claim 58, Virtanen teaches that said capture agent (ie., the oligonucleotide) contains an amino group (see column page 60, first paragraph).

Therefore, Virtanen teaches all limitations recited in claims 51, 52, and 58.

Response to Arguments

In page 22, first and second paragraphs of applicant's remarks, applicant argues that "[V]irtanen does not disclose a 'heat-treated active layer' and 'wherein non-covalently bound capture agents are selectively removed.' Thus, Applicants respectfully submit that Virtanen does not disclose all of the limitations of any of claims 51, 52, 58, and 61-66, as now amended".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because Virtanen does teach heat-treated active layer (see above rejection). Although Virtanen does not teach "non-covalently bound capture agents are

selectively removed" as recited in claim 51, Virtanen teaches that oligonucleotides are covalently attached to the solid support substrate (see page 60, first paragraph). Since "non-covalently bound capture agents are selectively removed" recited in claim 51 is a method step, it is known that the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (1998 or 2000) as applied to claims 51, 52, and 58 above, and further in view of Eggers *et al.*, (US Patent No. 5,891,630, published on April 6, 1999).

The teachings of Virtanen have been summarized previously, *supra.*

Virtanen does not disclose that said capture agent is a double stranded oligonucleotide sequence.

Eggers *et al.,* teach to attach a double stranded DNA on a solid support (see column 7, lines 58-67 and column 8, lines 1-23).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an optical bio-disc recited in claim 53 wherein said capture agent is a double stranded oligonucleotide sequence in view of the prior art of Virtanen and Eggers *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of oligonucleotide (ie., a single stranded oligonucleotide) from another kind of oligonucleotide (ie., a double stranded oligonucleotide) during the process of making an optical bio-disc recited in claim 53, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since either a single or double stranded oligonucleotide immobilized on a support has an ability to hybridizes to a complementary probe.

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

10. Claims 59-63, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (1998 or 2000) as applied to claims 51, 52, and 58 above, and further in view of Cohen *et al.,* (US 2002/0196435 A1, priority date: November 22, 2000).

The teachings of Virtanen have been summarized previously, *supra.*

Regarding claim 61, Virtanen teaches that said capture agent (ie., oligonucleotide side members) binds with an anchor agent (ie., cleavable spacer molecules) to thereby locate said anchor agent within said target zone (for Virtanen (1998), see Figures 1A and 2A and column 16, lines 51-67 or for Virtanen (2000), see pages 37 and 38).

Regarding claims 62, 63, 65, and 66, since claim 51 does not require that a dual bead complex is on the optical bio-disc and claims 62, 63, 65, and 66 is related to or further limit the dual bead complex recited in claim 51, claims 62, 63, 65, and 66 are anticipated by Virtanen.

Virtanen does not disclose that said heated-treated active layer is formed from a polystyrene-co-maleic anhydride and said amino group chemically reacts with said maleic anhydride to form a covalent bond thereby maintaining said capture agents within said target zone as recited in claims 59 and 60. However, Virtanen teaches that said capture agent (ie., the oligonucleotide) contains an amino group and is covalently attached to the active layer (see Figure 1A).

Cohen *et al.,* teach that capture layer (ie., said active layer) in an optical disk is formed by a polystyrene-co-maleic anhydride (see [0035]).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art

at the time the invention was made to have made an optical bio-disc recited in claims 59 and 60 wherein said active layer is formed from a polystyrene-co-maleic anhydride and said amino group chemically reacts with said maleic anhydride to form a covalent bond thereby maintaining said capture agents within said target zone in view of the prior art of Virtanen and Cohen *et al.*. One having ordinary skill in the art would have been motivated to do so because the simple substitution of one kind of material (ie., the material taught by Virtanen) from another kind of material (ie., a polystyrene-co-maleic anhydride taught by Cohen *et al.*,) during the process of making the active layer recited in claims 59 and 60, in the absence of convincing evidence to the contrary, would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made since said capture agent (ie., the oligonucleotide) contains an amino group has an ability to attach a polystyrene-co-maleic anhydride and the active layer taught by Virtanen and the active layer taught by Cohen *et al.,* are used for the same purpose (ie., attaching capture agents).

Furthermore, the motivation to make the substitution cited above arises from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Support for making the obviousness rejection comes from the M.P.E.P. at 2144.06, 2144.07 and 2144.09.

Also note that there is no invention involved in combining old elements is such a manner that these elements perform in combination the same function as set forth in the prior art without giving unobvious or unexpected results. *In re Rose* 220 F.2d. 459, 105 USPQ 237 (CCPA 1955).

Response to Arguments

In page 23, second and third paragraphs of applicant's remarks, applicant argues that "[C]laims 59 and 60 depend from independent claim 51, which has been amended to recite the phrase 'heat-treated active layer' and 'wherein non-covalently bound capture agents are selectively removed.' Further, claim 59 has been amended to cite that the active layer is 'heat-treated'. Applicants respectfully submit that neither Virtanen nor Cohen et al disclose a 'heat-treated active layer' and 'wherein non-covalently bound capture agents are selectively removed.' Thus, Virtanen in view of Cohen, does not disclose all of the limitations of claims 59 or 60".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection because Virtanen does teach heat-treated active layer (see above rejections under 35 U.S.C 102). Although Virtanen does not teach "non-covalently bound capture agents are selectively removed" as recited in claim 51, Virtanen teaches that oligonucleotides are covalently attached to the solid support substrate (see page 60, first paragraph). Since "non-covalently bound capture agents are selectively removed" recited in claim 51 is a method step, it is known that the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571) 272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu
Primary Examiner
November 22, 2005